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July 10, 2000

Ms. Kathy Eberhart
Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike, Suite 200 North
Rockville, MD 20852-1448
HFM 42

Dear Ms. Eberhart:

I am writing because on August 2, 2000 the Food and Drug Administration's Center for Biologics Evaluation and Research and Center for Devices and Radiological Health are sponsoring an open public meeting on Human Bone Allograft. The issue of classifying allograft bone as a device has been brewing for some time now. I know that I have written at least two letters to the Document Management Branch of the FDA concerning this important issue. Currently bone banks provide bone as tissue, and the FDA regulates this in terms of safety. If the FDA is successful in reclassifying allograft bone as a device, it would potentially remove from availability *tissue* which has been used for many years in the clinical setting. Over these many years that we have been using this allograft bone, it has been demonstrated to be safe and effective for situations where it is used. Specifically with regard to safety, bank bone is not immunogenic, and aside from one donor from which multiple organ transplants were obtained, there haven't been any reports of bank bone transmitting viral illnesses.

Those of us who care for children and adults with spinal deformities depend greatly on bone banks to provide sufficient allograft to be able to achieve a solid spinal fusion in these patients. Whether the bank bone is morselized, cancellous or corticocancellous chips, struts made of femoral, tibial, or fibular shafts, or whether the bone has been "worked" in some way to provide it with threads or other special shapes, really makes no difference – it is still bank bone. Additionally, those of us who take care of musculoskeletal tumor patients rely on allograft bone to be able to reconstruct the skeleton after tumor resection. As I mentioned previously, there is abundant literature to show that these allografts are effective and safe for use in these applications. It would be a great disservice to our patients if all of a sudden the FDA requires all this new regulation and documentation that might curtail the supply of this tissue for uses that I have described above.

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As a pediatric orthopaedic surgeon who has a busy practice that utilizes large amounts of bank bone, I urge you to reconsider any thought of subjecting allograft to the kind of regulatory process that medical devices are required to go through. I think that officials from your agency will see at the upcoming hearing that there is really absolutely no need for this kind of regulation to occur. I think one thing that people in your agency don't understand or perhaps are not aware of is that bone or devices are inanimate objects, and as such don't jump out of a bottle or a box into a patient by themselves. Frequently problems that arise from various implants or allografts occur because the indications for their use were not really met, the surgery was performed poorly, or for other technical reasons that had nothing to do with the implant or the graft itself. The FDA cannot possibly regulate that kind of problem, and by insisting on enforcing regulations that cannot address those problems, in the end doesn't help the situation but in fact makes it worse for those of us who have stringent and proper criteria for the use of these particular devices and grafts.

This is an important issue for myself and other physicians like me, and our patients.

Sincerely,

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